

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

In re: ORTHO EVRA® PRODUCTS
LIABILITY LITIGATION

Applies to All cases

) N.D. Ohio Case No. 1:06cv-40000

) MDL Docket No. 1742

) Judge David A. Katz

) **DEFENDANTS JOHNSON & JOHNSON,**
) **JOHNSON & JOHNSON**
) **PHARMACEUTICAL RESEARCH &**
) **DEVELOPMENT, LLC AND ORTHO-**
) **MCNEIL PHARMACEUTICAL, INC.'S**
) **ANSWER TO PLAINTIFFS' MASTER**
) **CONSOLIDATED COMPLAINT**

) **(JURY DEMAND ENDORSED HEREON)**

Defendants Johnson & Johnson, Johnson & Johnson Pharmaceutical Research & Development, LLC and Ortho-McNeil Pharmaceutical, Inc. ("Defendants"), by and through counsel, hereby respond to the allegations set forth in Plaintiffs' Master Consolidated Complaint for Individuals as follows:

ANSWER TO PARTIES, JURISDICTION AND VENUE

1. Defendants admit the allegations and averments set forth in Paragraph 1.
2. Defendants are without knowledge or information sufficient to form a belief regarding the truth of the averments set forth in Paragraph 2.
3. Defendants state that CMO-11 speaks for itself and deny any allegations or averments set forth in Paragraph 3.
4. Defendants admit that the Master Consolidated Complaint was filed in accordance with and subject to the provisions of CMO-11 and further answering, Defendants are without

knowledge or information sufficient to form a belief regarding the truth of any allegations or averments set forth in Paragraph 4.

5. Defendants admit that Johnson & Johnson is a New Jersey corporation with its principal place of business in New Jersey.

6. Defendants deny each and every allegation and averment set forth in Paragraph 6.

7. Defendants state that Johnson & Johnson is a holding company that does not transact or conduct business and therefore, Defendants deny each and every allegation and averment set forth in Paragraph 7.

8. Defendants deny each and every allegation and averment set forth in Paragraph 8.

9. Defendants deny each and every allegation and averment set forth in Paragraph 9.

10. Defendants admit that defendant Johnson & Johnson Pharmaceutical Research & Development, LLC is a New Jersey Limited Liability Company with its principal place of business in New Jersey.

11. Defendants admit that defendant Ortho-McNeil Pharmaceutical, Inc. and/or defendant Johnson & Johnson Pharmaceutical Research & Development, LLC designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, sold and placed into the stream of commerce the prescription medicine Ortho Evra® and further answering, deny each and every remaining allegation and averment set forth in Paragraph 11.

12. Defendants admit that defendant Johnson & Johnson Pharmaceutical Research & Development, LLC is part of Johnson & Johnson's "Family of Companies" and further answering, deny each and every remaining allegation and averment set forth in Paragraph 12.

13. Defendants deny each and every allegation and averment set forth in Paragraph 13.

14. Defendants state that defendant Johnson & Johnson Pharmaceutical Research & Development, LLC performs research and development work for the pharmaceutical business units of Johnson & Johnson and does not transact or conduct business and therefore, Defendants deny each and every allegation and averment set forth in Paragraph 14.

15. Defendants deny each and every allegation and averment set forth in Paragraph 15.

16. Defendants deny each and every allegation and averment set forth in Paragraph 16.

17. Defendants admit that defendant Ortho-McNeil Pharmaceutical, Inc. is a Delaware corporation with its principal place of business in New Jersey.

18. Defendants admit that defendant Ortho-McNeil Pharmaceutical, Inc. and/or defendant Johnson & Johnson Pharmaceutical Research & Development, LLC designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, sold and placed into the stream of commerce the prescription medicine Ortho Evra® and further answering, deny each and every remaining allegation and averment set forth in Paragraph 18.

19. Defendants admit that defendant Ortho-McNeil Pharmaceutical, Inc. is a wholly owned subsidiary of Johnson & Johnson.

20. Defendants are without knowledge or information sufficient to form a belief regarding the truth of the averments set forth in Paragraph 20.

21. Defendants deny for want of knowledge, information, and otherwise each and every allegation and averment set forth in Paragraph 21.

22. Defendants deny for want of knowledge, information, and otherwise each and every allegation and averment set forth in Paragraph 22.

ANSWER TO FACTUAL ALLEGATIONS

23. Defendants admit that the prescription medicine Ortho Evra® is a transdermal contraceptive patch designed to prevent pregnancy and further answering, Defendants deny each and every remaining allegation and averment set forth in Paragraph 23.

24. Defendants admit that defendant Ortho-McNeil Pharmaceutical, Inc. is described on Defendants' Website as "a pioneer and leader in contraception and women's health care, offering the broadest range of prescription birth control options . . ." and further answering, Defendants deny each and every remaining allegation and averment set forth in Paragraph 24.

25. Defendants admit that the prescription medicine Ortho Evra® is the first and only transdermal contraceptive patch on the market in the United States and further answering, Defendants deny each and every remaining allegation and averment set forth in Paragraph 25.

26. Defendants deny each and every allegation and averment set forth in Paragraph 26.

27. Defendants deny each and every allegation and averment set forth in Paragraph 27.

28. Defendants admit that defendant Johnson & Johnson Pharmaceutical Research & Development, LLC. filed a New Drug Application for Ortho Evra® with the FDA on or about

December 21, 2000, denoted as NDA 21-180 and further answering, Defendants deny each and every remaining allegation and averment set forth in Paragraph 28.

29. Defendants admit that the NDA for Ortho Evra® states that the intended prescription use of Ortho Evra® is for the prevention of pregnancy and further answering, Defendants deny each and every remaining allegation and averment set forth in Paragraph 29.

30. Defendants deny each and every allegation and averment set forth in Paragraph 30.

31. Defendants deny each and every allegation and averment set forth in Paragraph 31.

32. Defendants deny each and every allegation and averment set forth in Paragraph 32.

33. Defendants deny each and every allegation and averment set forth in Paragraph 33.

34. Defendants deny each and every allegation and averment set forth in Paragraph 34.

35. Defendants deny each and every allegation and averment set forth in Paragraph 35.

36. Defendants admit that clinical trials were conducted, pursuant to an FDA approved NDA, which were reviewed by the FDA prior to FDA approval of Ortho Evra® for prescription medicine use by physicians and further answering, Defendants deny each and every remaining allegation and averment set forth in Paragraph 36.

37. Defendants deny each and every allegation and averment set forth in Paragraph 37.

38. Defendants deny each and every allegation and averment set forth in Paragraph 38.

39. Defendants deny each and every allegation and averment set forth in Paragraph 39.

40. Defendants deny each and every allegation and averment set forth in Paragraph 40.

41. Defendants state that the actions and publications of the FDA speak for themselves and further answering, Defendants deny each and every allegation and averment set forth in Paragraph 41.

42. Defendants state that the actions and publications of the FDA speak for themselves and further answering, Defendants deny each and every allegation and averment set forth in Paragraph 42.

43. Defendants admit that on or about November 20, 2001, the FDA approved the use of Ortho Evra® as a prescription medicine for use by physicians for the prevention of pregnancy and further answering, Defendants deny each and every remaining allegation and averment set forth in Paragraph 43.

44. Defendants deny each and every allegation and averment set forth in Paragraph 44.

45. Defendants deny each and every allegation and averment set forth in Paragraph 45.

46. In response to the allegations and averments set forth in Paragraph 46, Defendants admit that such Paragraph contains certain language from the former Ortho Evra® package insert and, to the extent Paragraph 46 alleges improper conduct on the part of Defendants, deny such allegations and averments.

47. In response to the allegations and averments set forth in Paragraph 47, Defendants admit that such Paragraph contains certain language from the former Ortho Evra® package insert, and that they expected plaintiffs to read the package insert, further answering, Defendants deny for want of knowledge, information, and otherwise each and every remaining allegation and averment set forth in Paragraph 47.

48. In response to the allegations and averments set forth in Paragraph 48, Defendants admit that such Paragraph contains certain language from the former Ortho Evra® package insert and that they expected physicians to read the package insert, further answering, Defendants deny for want of knowledge, information, and otherwise each and every remaining allegation and averment set forth in Paragraph 48.

49. In response to the allegations set forth in Paragraph 49, Defendants admit that such Paragraph contains certain language from the former Ortho-Evra® package insert and, to the extent Paragraph 49 alleges improper conduct on the part of Defendants, deny such allegations and averments.

50. Defendants deny each and every allegation and averment set forth in Paragraph 50.

51. Defendants deny each and every allegation and averment set forth in Paragraph 51.

52. In response to the allegations set forth in Paragraph 52, Defendants admit that such Paragraph contains certain language from the former Ortho-Evra® package insert and, to the extent Paragraph 52 alleges improper conduct on the part of Defendants, deny such allegations and averments.

53. In response to the allegations set forth in Paragraph 53, Defendants admit that such Paragraph contains certain language from the former Ortho-Evra® package insert and, to the extent Paragraph 53 alleges improper conduct on the part of Defendants, deny such allegations and averments.

54. Defendants deny each and every allegation and averment set forth in Paragraph 54.

55. Defendants deny each and every allegation and averment set forth in Paragraph 55.

56. Defendants deny each and every allegation and averment set forth in Paragraph 56.

57. Defendants admit that the Ortho Evra® package insert contains information regarding adverse reactions involving clotting and further answering, Defendants deny each and every other allegation and averment set forth in Paragraph 57.

58. Defendants admit that the Ortho Evra® package insert contains information regarding adverse reactions involving clotting and further answering, Defendants deny each and every other allegation and averment set forth in Paragraph 58.

59. Defendants deny each and every allegation and averment set forth in Paragraph 59.

60. Defendants deny each and every allegation and averment set forth in Paragraph 60.

61. Defendants deny each and every allegation and averment set forth in Paragraph 61.

62. To the extent Paragraph 62 describes language in the Ortho Evra® label, Defendants state that the label speaks for itself and further answering, Defendants deny each and every allegation and averment set forth in Paragraph 62.

63. Defendants deny each and every allegation and averment set forth in Paragraph 63.

64. Defendants admit that as with all prescription medicine, adverse events are reported to the FDA by a variety of people and entities and further answering, Defendants deny each and every remaining allegation and averment set forth in Paragraph 64.

65. Defendants admit that as with all prescription medicine, adverse events are reported to the FDA by a variety of people and entities and further answering, Defendants deny each and every remaining allegation and averment set forth in Paragraph 65.

66. Defendants admit that as with all prescription medicine, adverse events are reported to the FDA by a variety of people and entities and further answering, Defendants deny each and every remaining allegation and averment set forth in Paragraph 66.

67. Defendants admit that as with all prescription medicine, adverse events are reported to the FDA by a variety of people and entities and further answering Defendants deny each and every remaining allegation and averment set forth in Paragraph 67.

68. Defendants deny each and every allegation and averment set forth in Paragraph 68.

69. Defendants deny that the risk of blood clots, pulmonary emboli, strokes, heart attacks, and deep vein thrombosis is significantly higher with Ortho Evra® and further answering, deny each and every allegation and averment set forth in Paragraph 69.

70. Defendants deny that the risk of blood clots, pulmonary emboli, strokes, heart attacks, and deep vein thrombosis is significantly higher with Ortho Evra® and further answering, deny each and every allegation and averment set forth in Paragraph 70.

71. Defendants admit that all prescription medicines, including Ortho Evra®, carry the risk of severe and life threatening complications and side affects, and deny the remaining allegations and averments set forth in Paragraph 71.

72. Defendants deny each and every allegation and averment set forth in Paragraph 72.

73. Defendants deny each and every allegation and averment set forth in Paragraph 73.

74. Defendants deny each and every allegation and averment set forth in Paragraph 74.

75. Defendants deny for want of knowledge, information, and otherwise each and every allegation and averment set forth in Paragraph 75.

76. Defendants deny that Ortho Evra® is defective and further answering, deny for want of knowledge, information, and otherwise each and every remaining allegation and averment set forth in Paragraph 76.

77. Defendants deny each and every allegation and averment set forth in Paragraph 77.

ANSWER TO FEDERAL REQUIREMENTS

78. The allegations contained in Paragraph 78 contain conclusions of law which are inapplicable to this action and therefore, no response is required. To the extent improper conduct on the part of Defendants is alleged, Defendants deny such allegations and averments.

79. The allegations contained in Paragraph 79 contain conclusions of law to which no response is required. To the extent improper conduct on the part of Defendants is alleged, Defendants deny such allegations and averments.

80. The allegations contained in Paragraph 80 contain conclusions of law to which no response is required. To the extent improper conduct on the part of Defendants is alleged, Defendants deny such allegations and averments.

81. The allegations contained in Paragraph 81 contain conclusions of law to which no response is required. To the extent improper conduct on the part of Defendants is alleged, Defendants deny such allegations and averments.

82. The allegations contained in Paragraph 82 contain conclusions of law to which no response is required. To the extent improper conduct on the part of Defendants is alleged, Defendants deny such allegations and averments.

83. The allegations contained in Paragraph 83 contain conclusions of law to which no response is required. To the extent improper conduct on the part of Defendants is alleged, Defendants deny such allegations and averments.

84. The allegations contained in Paragraph 84 contain conclusions of law to which no response is required. To the extent improper conduct on the part of Defendants is alleged, Defendants deny such allegations and averments.

85. The allegations contained in Paragraph 85 contain conclusions of law to which no response is required. To the extent improper conduct on the part of Defendants is alleged, Defendants deny such allegations and averments.

86. The allegations contained in Paragraph 86 contain conclusions of law to which no response is required. To the extent improper conduct on the part of Defendants is alleged, Defendants deny such allegations and averments.

ANSWER TO FIRST CAUSE OF ACTION AS AGAINST THE DEFENDANTS
(NEGLIGENCE)

87. Defendants incorporate by reference, as if fully set forth herein, the answers to Paragraphs 1 through 86 of Plaintiffs' Master Consolidated Complaint.

88. Defendants state that they were subject only to those duties imposed by applicable law and deny the allegations set forth in Paragraph 88 to the extent they suggest any different or greater duties and further answering, deny each and every allegation and averment set forth in Paragraph 88.

89. Defendants deny each and every allegation and averment set forth in Paragraph 89.

90. Defendants deny each and every allegation and averment set forth in Paragraph 90, including subsections (c) through (l).

91. Defendants deny each and every allegation and averment set forth in Paragraph 91.

92. Defendants deny each and every allegation and averment set forth in Paragraph 92 and controvert the prayer for relief set forth in Paragraph 92.

ANSWER TO SECOND CAUSE OF ACTION AS AGAINST THE DEFENDANTS
(NEGLIGENCE PER SE)

93. Defendants incorporate by reference, as if fully set forth herein, the answers to Paragraphs 1 through 92 of Plaintiffs' Master Consolidated Complaint.

94. Defendants state that they were subject only to those obligations imposed by applicable law and deny the allegations set forth in Paragraph 94 to the extent they suggest any different or greater duties or obligations and further answering, deny each and every allegation and averment set forth in Paragraph 94.

95. Defendants deny each and every allegation and averment set forth in Paragraph 95.

96. Defendants deny for want of knowledge, information, and otherwise each and every allegation and averment set forth in Paragraph 96.

97. Defendants deny each and every allegation and averment set forth in Paragraph 97 and controvert the prayer for relief set forth in Paragraph 97.

ANSWER TO THIRD CAUSE OF ACTION AS AGAINST THE DEFENDANTS
(STRICT PRODUCTS LIABILITY – DEFECTIVE DESIGN)

98. Defendants incorporate by reference, as if fully set forth herein, the answers to Paragraphs 1 through 97 of Plaintiffs' Master Consolidated Complaint.

99. Defendants admit that defendant Ortho-McNeil Pharmaceutical, Inc. and/or defendant Johnson & Johnson Pharmaceutical Research & Development, LLC designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, sold and

placed into the stream of commerce the prescription medicine Ortho Evra® and further answering, deny each and every remaining allegation and averment set forth in Paragraph 99.

100. Defendants deny each and every allegation and averment set forth in Paragraph 100.

101. Defendants deny each and every allegation and averment set forth in Paragraph 101.

102. Defendants admit that Ortho Evra® was expected to reach consumers without substantial change in the condition in which it was sold and marketed and further answering, Defendants deny for want of knowledge, information, and otherwise each and every remaining allegation and averment set forth in Paragraph 102.

103. Defendants deny each and every allegation and averment set forth in Paragraph 103, including subsections (a) through (g).

104. Defendants deny each and every allegation and averment set forth in Paragraph 104.

105. Defendants deny each and every allegation and averment set forth in Paragraph 105.

106. Defendants deny each and every allegation and averment set forth in Paragraph 106 and controvert the prayer for relief set forth in Paragraph 106.

ANSWER TO FOURTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS
(STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT)

107. Defendants incorporate by reference, as if fully set forth herein, the answers to Paragraphs 1 through 106 of Plaintiffs' Master Consolidated Complaint.

108. Defendants admit that defendant Ortho-McNeil Pharmaceutical, Inc. and/or defendant Johnson & Johnson Pharmaceutical Research & Development, LLC designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, sold and placed into the stream of commerce the prescription medicine Ortho Evra® and further answering, deny each and every remaining allegation and averment set forth in Paragraph 108.

109. Defendants admit that Ortho Evra® was expected to reach consumers without substantial change in the condition in which it was sold and marketed and further answering, Defendants deny for want of knowledge, information, and otherwise each and every remaining allegation and averment set forth in Paragraph 109.

110. Defendants deny each and every allegation and averment set forth in Paragraph 110, including subsections (a) through (h).

111. Defendants deny each and every allegation and averment set forth in Paragraph 111 and controvert the prayer for relief set forth in Paragraph 111.

ANSWER TO FIFTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS
(STRICT PRODUCTS LIABILITY – FAILURE TO WARN)

112. Defendants incorporate by reference, as if fully set forth herein, the answers to Paragraphs 1 through 111 of Plaintiffs' Master Consolidated Complaint.

113. Defendants deny each and every allegation and averment set forth in Paragraph 113.

114. Defendants are without knowledge or information sufficient to form a belief regarding the truth of the averments set forth in Paragraph 114.

115. Defendants deny that Ortho Evra® is defective and further answering, deny each and every allegation and averment set forth in Paragraph 115.

116. Defendants deny each and every allegation and averment set forth in Paragraph 116.

117. Defendants deny each and every allegation and averment set forth in Paragraph 117.

118. Defendants deny each and every allegation and averment set forth in Paragraph 118.

119. Defendants deny each and every allegation and averment set forth in Paragraph 119.

120. Defendants deny for want of knowledge, information, and otherwise each and every allegation and averment set forth in Paragraph 120.

121. Defendants deny for want of knowledge, information, and otherwise each and every allegation and averment set forth in Paragraph 121.

122. Defendants state that they are subject only to those duties imposed by applicable law and deny the allegations set forth in Paragraph 122 to the extent they suggest any different or greater duties and further answering, deny each and every allegation and averment set forth in Paragraph 122.

123. Defendants deny each and every allegation and averment set forth in Paragraph 123.

124. Defendants deny for want of knowledge, information, and otherwise each and every allegation and averment set forth in Paragraph 124.

125. Defendants deny for want of knowledge, information, and otherwise each and every allegation and averment set forth in Paragraph 125.

126. Defendants deny for want of knowledge, information, and otherwise each and every allegation and averment set forth in Paragraph 126.

127. Defendants deny each and every allegation and averment set forth in Paragraph 127 and controvert the prayer for relief set forth in Paragraph 127.

ANSWER TO SIXTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS
(BREACH OF EXPRESS WARRANTY)

128. Defendants incorporate by reference, as if fully set forth herein, the answers to Paragraphs 1 through 127 of Plaintiffs' Master Consolidated Complaint.

129. Defendants deny each and every allegation and averment set forth in Paragraph 129.

130. Defendants deny each and every allegation and averment set forth in Paragraph 130.

131. Defendants deny each and every allegation and averment set forth in Paragraph 131.

132. Defendants deny each and every allegation and averment set forth in Paragraph 132.

133. Defendants deny making express warranties and further answering deny for want of knowledge, information, and otherwise each and every allegation and averment set forth in Paragraph 133.

134. Defendants deny making express warranties and further answering deny for want of knowledge, information, and otherwise each and every allegation and averment set forth in Paragraph 134.

135. Defendants deny making express warranties and further answering deny for want of knowledge, information, and otherwise each and every allegation and averment set forth in Paragraph 135.

136. Defendants deny making express warranties and further answering deny for want of knowledge, information, and otherwise each and every allegation and averment set forth in Paragraph 136.

137. Defendants deny each and every allegation and averment set forth in Paragraph 137.

138. Defendants deny each and every allegation and averment set forth in Paragraph 138.

139. Defendants deny each and every allegation and averment set forth in Paragraph 139.

140. Defendants deny each and every allegation and averment set forth in Paragraph 140 and controvert the prayer for relief set forth in Paragraph 140.

ANSWER TO SEVENTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS
(BREACH OF IMPLIED WARRANTIES)

141. Defendants incorporate by reference, as if fully set forth herein, the answers to Paragraphs 1 through 140 of Plaintiffs' Master Consolidated Complaint.

142. Defendants admit that defendant Ortho-McNeil Pharmaceutical, Inc. and/or defendant Johnson & Johnson Pharmaceutical Research & Development, LLC designed, manufactured, marketed, distributed, supplied and sold the prescription medicine Ortho Evra® for the prevention of pregnancy and further answering, deny each and every remaining allegation and averment set forth in Paragraph 142.

143. Defendants deny each and every allegation and averment set forth in Paragraph 143.

144. Defendants deny each and every allegation and averment set forth in Paragraph 144.

145. Defendants deny each and every allegation and averment set forth in Paragraph 145.

146. Defendants deny for want of knowledge, information, and otherwise each and every allegation and averment set forth in Paragraph 146.

147. Defendants are without knowledge or information sufficient to form a belief regarding the truth of the averments set forth in Paragraph 147.

148. Defendants deny any wrongful conduct and further answering, deny each and every allegation and averment set forth in Paragraph 148.

149. Defendants deny each and every allegation and averment set forth in Paragraph 149.

150. Defendants deny each and every allegation and averment set forth in Paragraph 150.

151. Defendants deny each and every allegation and averment set forth in Paragraph 151.

152. Defendants deny each and every allegation and averment set forth in Paragraph 152 and controvert the prayer for relief set forth in Paragraph 152.

ANSWER TO EIGHTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS
(FRAUDULENT MISREPRESENTATION)

153. Defendants incorporate by reference, as if fully set forth herein, the answers to Paragraphs 1 through 152 of Plaintiffs' Master Consolidated Complaint.

154. Defendants deny each and every allegation and averment set forth in Paragraph 154.

155. Defendants deny each and every allegation and averment set forth in Paragraph 155.

156. Defendants deny each and every allegation and averment set forth in Paragraph 156.

157. Defendants deny each and every allegation and averment set forth in Paragraph 157.

158. Defendants deny any false representations and further answering, deny each and every allegation and averment set forth in Paragraph 158.

159. Defendants deny each and every allegation and averment set forth in Paragraph 159.

160. Defendants deny that Ortho Evra® was not sufficiently tested, is unsafe, defective, unreasonably dangerous, or lacked adequate or sufficient warnings and further answering, Defendants deny each and every allegation and averment set forth in Paragraph 160.

161. Defendants deny each and every allegation and averment set forth in Paragraph 161.

162. Defendants deny each and every allegation and averment set forth in Paragraph 162.

163. Defendants deny each and every allegation and averment set forth in Paragraph 163.

164. Defendants deny each and every allegation and averment set forth in Paragraph 164 and controvert the prayer for relief set forth in Paragraph 164.

ANSWER TO NINTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS
(FRAUDULENT CONCEALMENT)

165. Defendants incorporate by reference, as if fully set forth herein, the answers to Paragraphs 1 through 164 of Plaintiffs' Master Consolidated Complaint.

166. Defendants deny each and every allegation and averment set forth in Paragraph 166.

167. Defendants deny each and every allegation and averment set forth in Paragraph 167.

168. Defendants deny each and every allegation and averment set forth in Paragraph 168, including subsections (a) through (s).

169. Defendants deny that Ortho Evra® is defective and further answering, deny each and every allegation and averment set forth in Paragraph 169.

170. Defendants deny each and every allegation and averment set forth in Paragraph 170.

171. Defendants deny each and every allegation and averment set forth in Paragraph 171.

172. Defendants deny each and every allegation and averment set forth in Paragraph 172.

173. Defendants deny each and every allegation and averment set forth in Paragraph 173.

174. Defendants deny each and every allegation and averment set forth in Paragraph 174.

175. Defendants deny each and every allegation and averment set forth in Paragraph 175.

176. Defendants deny each and every allegation and averment set forth in Paragraph 176.

177. Defendants deny each and every allegation and averment set forth in Paragraph 177.

178. Defendants deny each and every allegation and averment set forth in Paragraph 178.

179. Defendants deny each and every allegation and averment set forth in Paragraph 179.

180. Defendants deny each and every allegation and averment set forth in Paragraph 180.

181. Defendants deny each and every allegation and averment set forth in Paragraph 181.

182. Defendants deny each and every allegation and averment set forth in Paragraph 182.

183. Defendants deny any concealment or omissions and further answering, deny each and every allegation and averment set forth in Paragraph 183.

184. Defendants deny each and every allegation and averment set forth in Paragraph 184.

185. Defendants deny each and every allegation and averment set forth in Paragraph 185 and controvert the prayer for relief set forth in Paragraph 185.

ANSWER TO TENTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS
(NEGLIGENT MISREPRESENTATION)

186. Defendants incorporate by reference, as if fully set forth herein, the answers to Paragraphs 1 through 185 of Plaintiffs' Master Consolidated Complaint.

187. Defendants state that they are subject only to those duties imposed by applicable law and deny the allegations set forth in Paragraph 187 to the extent they suggest any different or greater duties and further answering, deny each and every allegation and averment set forth in Paragraph 187.

188. Defendants deny each and every allegation and averment set forth in Paragraph 188.

189. Defendants deny each and every allegation and averment set forth in Paragraph 189.

190. Defendants deny each and every allegation and averment set forth in Paragraph 190.

191. Defendants deny each and every allegation and averment set forth in Paragraph 191 and controvert the prayer for relief set forth in Paragraph 191.

ANSWER TO ELEVENTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS
(FRAUD AND DECEIT)

192. Defendants incorporate by reference, as if fully set forth herein, the answers to Paragraphs 1 through 191 of Plaintiffs' Master Consolidated Complaint.

193. Defendants deny each and every allegation and averment set forth in Paragraph 193.

194. Defendants deny each and every allegation and averment set forth in Paragraph 194.

195. Defendants deny each and every allegation and averment set forth in Paragraph 195.

196. Defendants deny each and every allegation and averment set forth in Paragraph 196.

197. Defendants deny each and every allegation and averment set forth in Paragraph 197.

198. Defendants deny each and every allegation and averment set forth in Paragraph 198.

199. Defendants deny each and every allegation and averment set forth in Paragraph 199.

200. Defendants deny each and every allegation and averment set forth in Paragraph 200.

201. Defendants deny each and every allegation and averment set forth in Paragraph 201.

202. Defendants deny each and every allegation and averment set forth in Paragraph 202.

203. Defendants deny each and every allegation and averment set forth in Paragraph 203.

204. Defendants deny each and every allegation and averment set forth in Paragraph 204.

205. Defendants deny each and every allegation and averment set forth in Paragraph 205.

206. Defendants admit that defendants Johnson & Johnson Pharmaceutical Research & Development, LLC and Ortho McNeil Pharmaceutical, Inc. conducted research on Ortho-Evra® and further answering, deny each and every remaining allegation and averment set forth in Paragraph 206.

207. Defendants deny each and every allegation and averment set forth in Paragraph 207.

208. Defendants deny each and every allegation and averment set forth in Paragraph 208.

209. Defendants deny each and every allegation and averment set forth in Paragraph 209.

210. Defendants deny each and every allegation and averment set forth in Paragraph 210.

211. Defendants state that they are subject only to those duties imposed by applicable law and deny the allegations set forth in Paragraph 211 to the extent they suggest any different or greater duties and further answering, deny each and every allegation and averment set forth in Paragraph 211.

212. To the extent the statements in Paragraph 212 refer to a specific document, Defendants refer to that document for a fair representation of what it states and, to the extent wrongful conduct is alleged, Defendants deny each and every allegation and averment set forth in Paragraph 212.

213. To the extent the statements in Paragraph 213 refer to a specific document, Defendants refer to that document for a fair representation of what it states and, to the extent wrongful conduct is alleged, Defendants deny each and every allegation and averment set forth in Paragraph 213.

214. To the extent the statements in Paragraph 214 refer to a specific document, Defendants refer to that document for a fair representation of what it states and, to the extent wrongful conduct is alleged, Defendants deny each and every allegation and averment set forth in Paragraph 214.

215. Defendants deny each and every allegation and averment set forth in Paragraph 215.

216. Defendants deny each and every allegation and averment set forth in Paragraph 216.

217. Defendants deny each and every allegation and averment set forth in Paragraph 217.

218. Defendants deny each and every allegation and averment set forth in Paragraph 218.

219. Defendants deny each and every allegation and averment set forth in Paragraph 219.

220. Defendants deny each and every allegation and averment set forth in Paragraph 220.

221. Defendants deny each and every allegation and averment set forth in Paragraph 221.

222. Defendants deny any false claims or representations and further answering, deny each and every allegation and averment set forth in Paragraph 222.

223. Defendants deny any false claims or representations and further answering, deny each and every allegation and averment set forth in Paragraph 223.

224. Defendants deny each and every allegation and averment set forth in Paragraph 224.

225. To the extent the statements in Paragraph 225 refer to a specific document, Defendants refer to that document for a fair representation of what it states and, to the extent wrongful conduct is alleged, Defendants deny each and every allegation and averment set forth in Paragraph 225.

226. Defendants deny each and every allegation and averment set forth in Paragraph 226.

227. Defendants deny each and every allegation and averment set forth in Paragraph 227.

228. Defendants deny each and every allegation and averment set forth in Paragraph 228.

229. Defendants deny each and every allegation and averment set forth in Paragraph 229.

230. Defendants deny each and every allegation and averment set forth in Paragraph 230.

231. Defendants deny for want of knowledge, information, and otherwise each and every allegation and averment set forth in Paragraph 231.

232. Defendants admit that defendant Ortho-McNeil Pharmaceutical, Inc. utilized direct-to-consumer advertising to market, promote and advertise the prescription medicine Ortho Evra® and further answering, deny each and every remaining allegation and averment set forth in Paragraph 232.

233. Defendants deny for want of knowledge, information, and otherwise each and every allegation and averment set forth in Paragraph 233.

234. Defendants deny for want of knowledge, information, and otherwise each and every allegation and averment set forth in Paragraph 234.

235. Defendants deny each and every allegation and averment set forth in Paragraph 235.

236. Defendants deny for want of knowledge, information, and otherwise each and every allegation and averment set forth in Paragraph 236.

237. Defendants deny each and every allegation and averment set forth in Paragraph 237.

238. Defendants deny each and every allegation and averment set forth in Paragraph 238.

239. Defendants deny each and every allegation and averment set forth in Paragraph 239.

240. Defendants deny each and every allegation and averment set forth in Paragraph 240 and controvert the prayer for relief set forth in Paragraph 240.

**ANSWER TO TWELFTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS
(UNFAIR AND DECEPTIVE TRADE PRACTICES UNDER STATE LAW)**

241. Defendants incorporate by reference, as if fully set forth herein, the answers to Paragraphs 1 through 240 of Plaintiffs' Master Consolidated Complaint.

242. Defendants state that they are subject only to those duties imposed by applicable law and deny the allegations set forth in Paragraph 242 to the extent they suggest any different or greater duties and further answering, deny each and every allegation and averment set forth in Paragraph 242.

243. Defendants deny any deceptive conduct and further answering, deny each and every allegation and averment set forth in Paragraph 243.

244. Defendants deny any deceptive, unconscionable or fraudulent representations or material omissions and further answering, deny each and every allegation and averment set forth in Paragraph 244.

245. Defendants deny each and every allegation and averment set forth in Paragraph 245.

246. Defendants deny each and every allegation and averment set forth in Paragraph 246.

247. Defendants deny each and every allegation and averment set forth in Paragraph 247.

248. Defendants deny any misrepresentations or omissions and further answering, deny each and every allegation and averment set forth in Paragraph 248.

249. Defendants deny each and every allegation and averment set forth in Paragraph 249.

250. Defendants deny any unfair or deceptive trade practices and further answering, Defendants are without knowledge or information sufficient to form a belief regarding the truth of the remaining averments set forth in Paragraph 250.

251. Defendants deny each and every allegation and averment set forth in Paragraph 251.

252. Defendants deny each and every allegation and averment set forth in Paragraph 252 and controvert the prayer for relief set forth in Paragraph 252.

**ANSWER TO THIRTEENTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS
(MISREPRESENTATION BY OMISSION)**

253. Defendants incorporate by reference, as if fully set forth herein, the answers to Paragraphs 1 through 252 of Plaintiffs' Master Consolidated Complaint.

254. Defendants deny each and every allegation and averment set forth in Paragraph 254.

255. Defendants deny any concealment and further answering, deny each and every allegation and averment set forth in Paragraph 255.

256. Defendants deny each and every allegation and averment set forth in Paragraph 256.

257. Defendants deny any intentional misrepresentations or omissions and further answering, deny each and every allegation and averment set forth in Paragraph 257.

258. Defendants deny that Ortho Evra® is defective and further answering, deny each and every allegation and averment set forth in Paragraph 258.

259. Defendants deny each and every allegation and averment set forth in Paragraph 259 and controvert the prayer for relief set forth in Paragraph 259.

**ANSWER TO FOURTEENTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS
(CONSTRUCTIVE FRAUD)**

260. Defendants incorporate by reference, as if fully set forth herein, the answers to Paragraphs 1 through 259 of Plaintiffs' Master Consolidated Complaint.

261. Defendants deny each and every allegation and averment set forth in Paragraph 261.

262. Defendants deny that Ortho Evra® is defective and further answering, deny for want of knowledge, information, and otherwise each and every allegation and averment set forth in Paragraph 262.

263. Defendants deny making unqualified statements to induce plaintiffs to purchase the patch and, further answering deny for want of knowledge, information, and otherwise each and every allegation and averment set forth in Paragraph 263.

264. Defendants deny each and every allegation and averment set forth in Paragraph 264.

265. Defendants deny each and every allegation and averment set forth in Paragraph 265.

266. Defendants deny each and every allegation and averment set forth in Paragraph 266 and controvert the prayer for relief set forth in Paragraph 266.

**ANSWER TO FIFTEENTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS
(NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS)**

267. Defendants incorporate by reference, as if fully set forth herein, the answers to Paragraphs 1 through 266 of Plaintiffs' Master Consolidated Complaint.

268. Defendants deny each and every allegation and averment set forth in Paragraph 268.

269. Defendants state that they are subject only to those duties imposed by applicable law and deny the allegations set forth in Paragraph 269 to the extent they suggest any different or greater duties and further answering, deny each and every allegation and averment set forth in Paragraph 269.

270. Defendants deny each and every allegation and averment set forth in Paragraph 270 and controvert the prayer for relief set forth in Paragraph 270.

271. Defendants deny each and every allegation and averment set forth in Paragraph 271.

**ANSWER TO SIXTEENTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS
(INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS)**

272. Defendants incorporate by reference, as if fully set forth herein, the answers to Paragraphs 1 through 271 of Plaintiffs' Master Consolidated Complaint.

273. Defendants deny each and every allegation and averment set forth in Paragraph 273.

274. Defendants deny each and every allegation and averment set forth in Paragraph 274.

275. Defendants deny each and every allegation and averment set forth in Paragraph 275.

276. Defendants deny each and every allegation and averment set forth in Paragraph 276.

**ANSWER TO SEVENTEENTH CAUSE OF ACTION AS AGAINST THE
DEFENDANTS
(GROSS NEGLIGENCE/MALICE)**

277. Defendants incorporate by reference, as if fully set forth herein, the answers to Paragraphs 1 through 276 of Plaintiffs' Master Consolidated Complaint.

278. Defendants deny any wrongs and further answering, deny each and every allegation and averment set forth in Paragraph 278.

279. Defendants deny each and every allegation and averment set forth in Paragraph 279 and controvert the prayer for relief set forth in Paragraph 279.

**ANSWER TO EIGHTEENTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS
(LOSS OF CONSORTIUM, IF APPROPRIATE)**

280. Defendants incorporate by reference, as if fully set forth herein, the answers to Paragraphs 1 through 279 of Plaintiffs' Master Consolidated Complaint.

281. Defendants deny causing any injury and state that they are without knowledge or information sufficient to form a belief regarding the truth of the averments set forth in Paragraph 281.

282. Defendants deny any misconduct and further answering deny for want of knowledge, information, and otherwise each and every allegation and averment set forth in Paragraph 282.

283. Defendants deny each and every allegation and averment set forth in Paragraph 283.

284. Defendants deny each and every allegation and averment set forth in Paragraph 284.

285. Defendants deny each and every allegation and averment set forth in Paragraph 285.

286. Defendants deny each and every allegation and averment set forth in Paragraph 286.

**ANSWER TO NINETEENTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS
(PER QUOD, IF APPROPRIATE)**

287. Defendants incorporate by reference, as if fully set forth herein, the answers to Paragraphs 1 through 286 of Plaintiffs' Master Consolidated Complaint.

288. The allegations contained in Paragraph 288 contain conclusions of law to which no response is required. To the extent improper conduct on the part of Defendants is alleged, Defendants deny such allegations and averments.

289. Defendants deny each and every allegation and averment set forth in Paragraph 289 and controvert the prayer for relief set forth in Paragraph 289.

290. Defendants deny each and every allegation and averment set forth in Paragraph 290.

**ANSWER TO TWENTIETH CAUSE OF ACTION AS AGAINST THE DEFENDANTS
(WRONGFUL DEATH, IF APPROPRIATE)**

291. Defendants incorporate by reference, as if fully set forth herein, the answers to Paragraphs 1 through 290 of Plaintiffs' Master Consolidated Complaint.

292. Defendants deny each and every allegation and averment set forth in Paragraph 292.

293. Defendants are without knowledge or information sufficient to form a belief regarding the truth of the averments set forth in Paragraph 293.

294. Defendants deny any wrongful conduct and further answering, each and every allegation and averment set forth in Paragraph 294.

295. Defendants are without knowledge or information sufficient to form a belief regarding the truth of the averments set forth in Paragraph 295.

296. Defendants deny each and every allegation and averment set forth in Paragraph 296 and controvert any prayer for relief set forth in Paragraph 296.

ANSWER TO TWENTY-FIRST CAUSE OF ACTION AS AGAINST THE
DEFENDANTS
(SURVIVAL ACTION, IF APPROPRIATE)

297. Defendants incorporate by reference, as if fully set forth herein, the answers to Paragraphs 1 through 296 of Plaintiffs' Master Consolidated Complaint.

298. Defendants deny each and every allegation and averment set forth in Paragraph 298.

299. Defendants are without knowledge or information sufficient to form a belief regarding the truth of the averments set forth in Paragraph 299.

300. Defendants deny each and every allegation and averment set forth in Paragraph 300 and controvert any prayer for relief set forth in Paragraph 300.

ANSWER TO TWENTY-SECOND CAUSE OF ACTION AS AGAINST THE
DEFENDANTS
(MEDICAL MONITORING)

301. Defendants incorporate by reference, as if fully set forth herein, the answers to Paragraphs 1 through 300 of Plaintiffs' Master Consolidated Complaint.

302. Defendants deny each and every allegation and averment set forth in Paragraph 302.

303. Defendants deny each and every allegation and averment set forth in Paragraph 303 and controvert any prayer for relief set forth in Paragraph 303.

ANSWER TO TWENTY-THIRD CAUSE OF ACTION AS AGAINST THE
DEFENDANTS
(PUNITIVE DAMAGES)

304. Defendants incorporate by reference, as if fully set forth herein, the answers to Paragraphs 1 through 303 of Plaintiffs' Master Consolidated Complaint.

305. Defendants deny that Ortho Evra® is inherently more dangerous than a contraceptive pill and further answering, deny each and every allegation and averment set forth in Paragraph 305.

306. Defendants deny each and every allegation and averment set forth in Paragraph 306.

307. Defendants deny any misrepresentation and further answering, each and every allegation and averment set forth in Paragraph 307.

308. Defendants deny each and every allegation and averment set forth in Paragraph 308.

309. Defendants deny each and every allegation and averment set forth in Paragraph 309.

310. Defendants deny each and every allegation and averment set forth in Paragraph 310.

311. Defendants deny each and every allegation and averment set forth in Paragraph 311.

312. Defendants deny each and every allegation and averment set forth in Paragraph 312.

313. Defendants deny that Ortho Evra® is defective or unreasonably dangerous and further answering, deny each and every allegation and averment set forth in Paragraph 313.

314. Defendants deny each and every allegation and averment set forth in Paragraph 314.

315. Defendants deny any failure to disclose information and further answering, each and every allegation and averment set forth in Paragraph 315.

316. Defendants deny each and every allegation and averment set forth in Paragraph 316 and controvert the prayer for relief set forth in Paragraph 316.

317. Defendants deny each and every allegation and averment set forth in Paragraph 317.

FIRST AFFIRMATIVE DEFENSE

318. The Master Consolidated Complaint fails to state a claim or claims upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

319. Some or all of Plaintiffs' claims are barred by the statute of limitations and/or statute of repose.

THIRD AFFIRMATIVE DEFENSE

320. Some or all of Plaintiffs' claims are barred by the doctrines of waiver, laches, and/or estoppel.

FOURTH AFFIRMATIVE DEFENSE

321. Some or all of Plaintiffs' claims are barred by the doctrines of informed consent and release.

FIFTH AFFIRMATIVE DEFENSE

322. Plaintiffs' claims are barred because any alleged damages, if any are proven, were not proximately caused by any acts or omissions of any of the Defendants.

SIXTH AFFIRMATIVE DEFENSE

323. If Plaintiffs suffered any of the injuries, losses and damages alleged, then said injuries, losses and damages were a direct and proximate result of responsible, superseding, and/or intervening causes.

SEVENTH AFFIRMATIVE DEFENSE

324. The injuries and damages claimed by Plaintiffs, if any, were caused in whole or in part by the negligence, fault, or other culpable conduct of persons other than the Defendants, or otherwise by the acts or omissions of persons over whom these Defendants have no control or right of control.

EIGHTH AFFIRMATIVE DEFENSE

325. Upon information and belief, if the injuries referred to in the Master Consolidated Complaint were caused by Ortho Evra®, which is denied, the injuries may be the result of idiosyncratic reactions to the product.

NINTH AFFIRMATIVE DEFENSE

326. Plaintiffs' alleged injuries may be a result of pre-existing and/or unrelated medical conditions for which these Defendants are not responsible.

TENTH AFFIRMATIVE DEFENSE

327. The claims of Plaintiffs should be dismissed, reduced, offset, or barred in accordance with any and all applicable principles of comparative negligence.

ELEVENTH AFFIRMATIVE DEFENSE

328. The claims of Plaintiffs should be dismissed, reduced, offset, or barred in accordance with any and all applicable principles of contributory negligence in failing to exercise due and proper care under the existing circumstances and conditions.

TWELFTH AFFIRMATIVE DEFENSE

329. Plaintiffs failed to exercise reasonable care and diligence to mitigate injuries and damages, if any.

THIRTEENTH AFFIRMATIVE DEFENSE

330. The injuries and damages alleged by Plaintiffs are or may be due to Plaintiffs' assumption of the risk of use of Ortho Evra®, if any, thereby barring Plaintiffs from recovery.

FOURTEENTH AFFIRMATIVE DEFENSE

331. Plaintiffs' claims are barred by Plaintiffs' abuse and/or misuse of the Ortho Evra® product.

FIFTEENTH AFFIRMATIVE DEFENSE

332. Plaintiffs' claims are barred by the "state of the art" and "state of scientific knowledge" defenses.

SIXTEENTH AFFIRMATIVE DEFENSE

333. The duty to warn, if any, extends only to Plaintiffs' physicians and not directly to Plaintiffs. Therefore, Plaintiffs' claims are barred in whole or in part by the Learned Intermediary Doctrine.

SEVENTEENTH AFFIRMATIVE DEFENSE

334. Plaintiffs' claims are barred in whole or part because Ortho Evra® was at all times properly prepared, packaged, and distributed, and was not defective or unreasonably dangerous.

EIGHTEENTH AFFIRMATIVE DEFENSE

335. The United States Food and Drug Administration approved the labeling for Ortho Evra®, and the marketing and/or distribution of Ortho Evra® conformed with FDA requirements and all other applicable statutes at all times pertinent to the Master Consolidated Complaint. *See*, 21 U.S.C. §301 *et seq.* *See also*, 71 Fed. Reg. 3922 (January 24, 2006).

NINETEENTH AFFIRMATIVE DEFENSE

336. Because the FDA approved Ortho Evra®, Plaintiffs' claims that Defendants are strictly liable are barred under the Restatement (Second) of Torts: Products Liability § 402A and comments thereto, and/or the Restatement (Third) of Torts: Products Liability §§ 2, 4 and 6 and comments thereto.

TWENTIETH AFFIRMATIVE DEFENSE

337. Ortho Evra® is safe when used as directed, and Defendants reasonably assumed that the warnings would be read and heeded; therefore, the product is neither defective nor unreasonably dangerous pursuant to Restatement (Second) of Torts § 402(A), Comment j.

TWENTY-FIRST AFFIRMATIVE DEFENSE

338. Plaintiffs' claims are preempted by federal and state law and any regulations or rules promulgated thereunder, including the Federal Food, Drug and Cosmetic Act and the Medical Device Amendments thereto. The granting of the relief prayed for would impede, impair, frustrate or burden the effectiveness of such federal law and would violate the Supremacy Clause (Art. VI, Clause 2) of the United States Constitution.

TWENTY-SECOND AFFIRMATIVE DEFENSE

339. The Master Consolidated Complaint and each cause of action thereof are barred by the doctrine of immunity for prescription drugs and medical devices, by the Commerce Clause, Article I, Section 8, of the Constitution of the United States as an undue burden upon interstate commerce and/or by the preemption doctrine in that Plaintiffs have asserted claims for relief which, if granted, would constitute an impermissible burden by this court on federal laws, regulations and polity relating to the development and marketing of prescription drugs and medical devices in violation of the Supremacy Clause, Article IV, Clause 2 of the Constitution of the United States.

TWENTY-THIRD AFFIRMATIVE DEFENSE

340. To the extent Plaintiffs' claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001).

TWENTY-FOURTH AFFIRMATIVE DEFENSE

341. Any imposition of punitive damages in this case against Defendants is barred to the extent that the manner in which such punitive damages are calculated violates the

Constitution of the United States and/or the Constitution of the state whose law is deemed to apply.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

342. Any award of punitive damages in this case against Defendants is barred to the extent that the amount of such an award violates the Constitution of the United States and/or the Constitution of the state whose law is deemed to apply.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

343. Defendants did not make to Plaintiffs nor did they breach any express or implied warranties and/or breach any warranties created by law. To the extent that Plaintiffs rely on any theory of breach of warranty, such claims are barred by applicable law, and for lack of privity with Defendants and/or for failure of Plaintiffs, or Plaintiffs' representatives, to give timely notice to Defendants of any alleged breach of warranty. Defendants further specifically plead as to any breach of warranty claim all affirmative defenses under the Uniform Commercial Code existing and which may arise in the future, as enacted in the states whose laws are deemed to apply in these cases.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

344. Plaintiffs' claims are barred, in whole or in part, because the advertisements and labeling with respect to Ortho Evra® were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the Constitution of the United States.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

345. Defendants did not violate any unfair or deceptive trade practice acts or other statutes under state law and/or these acts and statutes are not applicable to these matters and/or to these Plaintiffs.

TWENTY-NINTH AFFIRMATIVE DEFENSE

346. Plaintiffs' claims and/or alleged damages are barred and/or limited by the provisions of the tort reform acts and/or statutes enacted in the states whose laws are deemed to apply in these cases.

THIRTIETH AFFIRMATIVE DEFENSE

347. Plaintiffs have failed to plead fraudulent misrepresentation, fraudulent concealment, negligent misrepresentation, fraud and deceit, misrepresentation by omission and constructive fraud, with specificity.

THIRTY-FIRST AFFIRMATIVE DEFENSE

348. Defendants are entitled to setoffs for all amounts paid, payable by or available from collateral sources.

THIRTY-SECOND AFFIRMATIVE DEFENSE

349. Plaintiffs' claims should be diminished in whole or in part in the amounts paid to Plaintiffs by any party or non-party with whom Plaintiffs have settled or may settle.

THIRTY-THIRD AFFIRMATIVE DEFENSE

350. To the extent not incorporated above, Defendants raise all affirmative defenses available under the laws of the state in which the alleged causes of action arose.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

351. Defendants specifically reserve the right to amend their Answer by adding defenses, counterclaims, cross claims or by instituting third party actions as additional facts are obtained.

WHEREFORE, having fully answered, Defendants Johnson & Johnson, Johnson & Johnson Pharmaceutical Research & Development, LLC and Ortho-McNeil Pharmaceutical, Inc. specifically controvert Plaintiffs' Prayer for Relief, including Paragraphs 1 through 9.

Respectfully submitted,

/s/ Susan Sharko

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Johnson & Johnson Pharmaceutical Research &
Development, LLC and Ortho-McNeil
Pharmaceutical, Inc.

JURY DEMAND

Defendants Johnson & Johnson, Johnson & Johnson Pharmaceutical Research & Development, LLC and Ortho-McNeil Pharmaceutical, Inc. hereby demand a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

CERTIFICATE OF SERVICE

I hereby certify that on June 12, 2007, a copy of the foregoing was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

/s/ Julie A. Callsen

Attorney for Defendants Johnson & Johnson,
Johnson & Johnson Pharmaceutical Research
& Development, LLC and Ortho-McNeil
Pharmaceutical, Inc.